



Health Facilities Planning & Development

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Bart Eggen, Director
Office of Certification and Enforcement
Department of Health
P.O. Box 47852
310 Israel Road
Tumwater, WA 98504

Dear Bart:

On behalf of the hospitals listed below, thank you for the opportunity to submit comments on the Health Management Associates (HMA) report entitled "Elective Percutaneous (PCI) Coronary Intervention Without On-Site Cardiac Surgery".

The hospitals listed below are fully knowledgeable of, and stand in full consensus with, the evidence-based data contained within the literature cited by HMA. However, many of HMA's recommendations do not, and can not be tied back to the evidence. Unfortunately, and beyond the actual review of the literature, the faulty "methodology" used by the authors calls into serious question their opinions and subjective conclusions and recommendations. These opinions and subjective conclusions are particularly troubling given the authors' lack of cardiac expertise, knowledge of Washington State's current cardiac delivery system, and their clearly limited, non-representative conversations with select providers which influenced and guided their personal conclusions. In addition, a stronger emphasis was placed on guidelines (Level C data) than on a review of Level B data (the best available evidence).

Further, HMA erred in concluding that the absence of Level A data was definitive. HMA's conclusion is in direct contradiction to principles of evidence-based medicine. See for example:

Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. Evidence-based medicine is not restricted to randomised trials and meta-analyses. It involves tracking down the best external evidence with which to answer our clinical questions. Source: Sackett, D.L. et al. (1996) Evidence based medicine: what it is and what it isn't. British Medical Journal. 312 (7023), 13 January, 71-72). This paper is also available on the Web at: <http://cebim.jr2.ox.ac.uk/ebmisint.html>

And

*Evidence-based medicine (EBM) is an approach to health care that promotes the collection, interpretation, and integration of valid, important and applicable patient-reported, clinician-observed, and research-derived evidence. **The best available evidence**, moderated by patient circumstances and preferences, is applied to improve the quality of clinical judgments.* Source: McKibbin, K.A. et al. (1995) The medical literature as a resource for evidence based care. Working Paper from the Health Information Research Unit, McMaster University, Ontario, Canada. This paper is also available on the Web at <http://hiru.mcmaster.ca/hiru/medline/asis-pap.htm>

All Level B studies cited in the HMA report, except one, found no significant difference in outcomes between hospitals with and without on-site cardiac surgery—**at any volume level**. The exception was a study that only found a difference in very low volume hospitals (performing 50 or fewer Medicare PCIs per year - which equates to approximately 100 total procedures per year). Again, while not classified as “Level A” studies, they do add to the overwhelming wealth of data that taken together form the “*best external evidence with which to answer our clinical questions.*”

In addition, even the Level C data that HMA relied upon was not the most recent and relevant. The authors relied on the 2005 ACC/AHA¹ Guidelines and only cherry-picked certain recommendations out of the more recent and more relevant 2007 SCAI guidelines — again, not an evidence-based approach.

Given each of the above problems, the Department of Health (Department) should request that HMA revise the report to reflect data and not opinions, place the appropriate emphasis on Level B data, remove any reference to Washington-specific need (as there is absolutely no information in the report to ascertain how population-based, community, and facility-specific need analyses were undertaken), and fully include the most recent Level C data available. In the absence of a formal revision to the report, we note that SB 2304 only requires the Department to “consider” the results of the report in its rule-development.

A sampling of our specific concerns with the HMA report is summarized below:

Misunderstanding of Evidence-Based Principles:

- The fact that HMA recommended against allowing any elective PCIs in hospitals without on-site cardiac surgery because no Level A evidence exists, when there is a wealth of Level B evidence, calls into question HMA’s understanding of the basic principles of evidence based medicine, as well as their objectivity. HMA’s presenters

¹ These Guidelines were produced in collaboration with, among others, the Society for Cardiovascular Angiography Interventions.

at the September 12 meeting acknowledged how little of their own current internal medicine practices are based on Level A evidence; yet they elected to set a bar for this Report that would in their respective practices seriously hinder their ability to provide needed and necessary care.

- The authors end their Introduction with the following statement: *“In this context the lack of well powered “level of Evidence A” randomized prospective studies concerning the comparative safety and efficacy of elective PCIs in hospitals with and without on-site cardiac surgery has contributed to the reluctance of expert panels, professional societies and governmental regulatory agencies to fully endorse and permit the provisions of elective PCI in hospitals without on-site cardiac surgery.”* This statement is misleading. Expert panels and professional societies around the world have both endorsed and/or acknowledged that elective PCIs are being performed in hospitals without on-site cardiac surgery. Additionally, in 37 states elective PCIs are performed in hospitals without on-site surgery outright, through administrative exception or through pilot/demonstration projects. Another 5 states are currently reviewing their regulations regarding elective PCI in hospitals without on-site surgery. Washington, which was a bellwether state in relation to emergency PCI has fallen far behind the curve, and our residents are the worse for it.

Uninformed and Unsubstantiated Opinions:

- Some examples of opinions, without data to substantiate them, include:
 - The Report goes far beyond the statement of work and makes a blanket conclusion about the lack of need for any additional PCI programs in Washington. Not only did the authors fail to cite any data to support their extraordinary opinion, it is clear from reading the Report that they did not consider issues regarding potential maldistribution of existing providers, the effect of door to balloon time on outcomes, traffic congestion, EMS delivery concerns, rurality, and basic cardiology and emergency coverage in Washington’s communities.
 - The Report also renders conclusions regarding emergency PCI recommending that *“The State of Washington should formally consider the designating of selected regional hospitals with on-site cardiac surgery as primary PCI ‘centers of excellence’ (similar to centralized Level I Trauma Centers) to which patients with Acute Myocardial Infarction and Acute Coronary Syndromes would be directly transported bypassing other hospitals.”* This recommendation is provided with no data or rationale to support it and again demonstrates a complete lack of understanding of the current emergency cardiac delivery system in Washington. It is also far outside the scope of the statement of work, and flies in the face of a wealth of (including Level A evidence) demonstrating the need for, and appropriateness of local and immediate access to emergency (primary) angioplasty.

Largely One-Sided Conversations with Select Providers Influenced and Guided the Authors' Conclusions:

- “Data” used by the authors in developing many of their conclusions included interviews with a few hospitals in Washington State. While unexpected, we could understand why they might want additional information on Washington’s cardiac delivery system. However, we have learned that they only communicated with:

Existing Elective PCI programs: Southwest Washington Medical Center (Clark County), Yakima Regional Medical Center (Yakima), Kadlec Medical Center (Benton), University of Washington Medical Center/Hospital (mainly about fellowship training programs. Without current Elective PCI program: Capital Medical Center (Thurston), Yakima Valley Medical Center (Yakima), Kennewick General Hospital (Benton), Valley Hospital and Medical Center (Spokane – very brief phone call). Both with and without elective PCI programs: Providence Health and Services Hospitals in Washington (primarily e-mail communication).

Source: September 17, 2007 email from Jack Raba to the Department.

- From questions posed at the September 12 meeting, we know that the only physician HMA spoke with was at UWMC. Unfortunately, no rural or suburban hospitals or cardiologists with access concerns were contacted. In addition, and as I understand from some of the hospitals that were contacted, the relevant questions about patient care, quality, outcomes and community need were not raised. This kind of subjective, limited and random interview process falls far short of the “evidence-based” bar that the authors were contracted to review. If the authors wanted input from hospitals they should have developed and administered an objective tool that was sent to, or used to interview each hospital or a truly representative sample. The clearly skewed data collection process, unfortunately, calls into question every author opinion rendered in the report. The irony of the situation should also be noted: the authors set an incredibly high bar for the literature and formal evidence and then resorted to a primitive and fundamentally flawed process to gain Washington-specific information.

Ignorance and Misinformation of the Current Washington Delivery System:

- The Introduction to the Report states that allowing the performance of elective PCIs in hospitals without on-site cardiac surgery will increase the overall utilization of PCIs. This assumption, unsubstantiated by data, ignores the key driver for the legislation behind the evidence-based review – and again reflects the authors misunderstanding of the current system in Washington. The specific and relevant situation in Washington resulting in the legislation is not to increase overall utilization but instead to:

- Allow hospitals without on-site cardiac surgery that already have established programs and perform the most difficult of emergency PCI cases (patients with Acute Myocardial Infarction or AMI) to also be able to perform PCIs on all patients, particularly on unstable but non AMI patients. Clinically, these patients have intermediate coronary syndrome. Currently, these patients most often present in the community hospital's emergency department and after having a diagnostic catheterization at the presenting hospital are transferred to a surgical hospital. Allowing, under certain circumstances (and when need can be demonstrated) these procedures to be performed in the community hospital will reduce adverse patient outcomes, duplicative testing, avoid an unnecessary transfer, reduce costs and improve care delivery.
 - Allow rural "hub" hospitals that have been unable to develop and/or are struggling to sustain a life-saving emergency program (largely because interventional-trained cardiologists, already in high demand nationally, are unwilling to practice in a community wherein they cannot practice as trained) to also perform elective PCIs. The combined volume will allow an economically viable comprehensive interventional cardiology service to be initiated when need is demonstrated.
- HMA's review of the public health environment under which they are making these recommendations focuses mainly on general statistics and overall trends without focusing on the relevant. Quite simply, HMA missed the mark. Instead of focusing on general, national statements, HMA should have focused on the health environment in Washington. The current situation in Washington appeared to be unknown to the authors. The reality of Washington is that:
- Most emergency PCI hospitals (those without on-site cardiac surgery programs) have been performing PCIs in emergency situations for nearly 15 years.
 - These very same hospitals and their communities face daily challenges with financial sustainability, cath lab staffing and recruitment and retention of cardiologists in large part because they are forced to transfer presenting non-AMI patients. Hence, they do not have sufficient volume in which to sustain a full, comprehensive cardiac program. At its core, this adversely affects the ability to offer basic cardiology care in Washington, and serves to limit availability to cardiology during acute episodes where all evidence concludes that "time is heart muscle".
 - There is a significant pool of patients who do not meet the definition of "emergency" but who are unstable and currently being subjected to duplicative procedures, unnecessary transfers, delays in care, additional costs and undue risk.
 - An additional reality is that Washington is a certificate of need State. As such, the Department has the authority to authorize specific evidence-based quality standards in which to ensure quality programs. Much of the general conclusions in the report regarding need, staffing, existing

providers, etc. are issues that should be appropriately addressed in response to a specific application in a specific community. This is the purpose and function of the Certificate of Need Program. Blanket and uninformed statements are unacceptable.

- HMA also stated that *“40% of selective PCI programs could fall below minimum or optimal volume standards if new programs”* were started. Absolutely no data was provided in support of this statement. Again, the purpose of certificate of need would be to ensure that, assuming need, existing providers are not unnecessarily impacted.

Inconsistent and Questionably Selective Use of Level B and C Evidence:

- When the authors defined the circumstances under which elective PCI could be performed in hospitals without on-site cardiac surgery, their recommendations did not follow the data cited— and even in the data they referenced (e.g. the SCAI Report) they cherry picked certain data to support their contentions and ignored others. A key example of this was related to volume standards. In the Executive Summary of the Report they state *“the applicant hospital must submit an objective plan to achieve minimum PCI volume standards >300 by the end of year two and optimal volumes >400 by year 3.”* In Section VI of the Report, they recommend a minimum annual PCI volume of >300 and an optimal annual volume of >400, and then go on to state, *“New programs...should achieve the minimum annual volumes within 2 years.”* The authors state that this recommendation was based on a “balanced review of the literature”. This statement is not accurate.
- With the exception of one study, the Level B studies cited that compared outcomes and volumes in hospitals with and without on-site cardiac surgery, **found no difference in outcome**. The only study that did report a difference found differences in outcomes in facilities with volumes of <50 Medicare PCIs per year (or approximately 100 total procedures).
- The most recent, relevant and “balanced review” of the data on this issue exists in the SCAI Report (which the authors used as rationale for some of their recommendations but not this specific recommendation). This report states: ***“Based on the available data and in concordance with the 2005 ACC/AHA/SCAI guideline update and other guidelines, it is recommended that facilities performing both primary and elective procedures without on-site surgery perform a minimum of 200 PCI/year. Programs with <200 PCI/year should be reviewed on an individual basis.”*** It continues to state that: ***“we recommend that each country or state review this issue, and establish an absolute minimum annual case volume below which a PCI program must close under any circumstance. In the United States, this minimum should be 150 PCI/year for a program offering both primary and elective PCIs.”*** It is a mystery as to why HMA elected to neither cite nor reference this latest 2007 expert recommendation in this particular recommendation.

Other Recommendations are Lacking or Insufficient:

- While our above comments focus largely on the literature related to volume, the Report is unfortunately littered with other recommendations that have no basis in evidence. Most notably this includes the recommendation regarding a minimum of two catheterization laboratories.
- Additionally, and in conflict with the final RFP issued by the Department, HMA failed to address completely and/or substantiate with data the following:
 - Minimum levels of ancillary support services within the community or other local hospitals.
 - Maximum transport times based on clinical outcomes to a heart surgery hospital site, including door to dilation time, cath lab to heart surgery operating suite, and weather and traffic conditions.
 - Allowable impacts to existing programs.
 - Relationship between a hospital's ability to perform elective interventions and its ability to sustain primary interventional programs in the community.
- At the September 12 meeting, HMA itself agreed that its Cost and Financial sections were weak. Absolutely no data or analysis was done on:
 - The quantifiable increase or decrease in the cost of interventional procedures resulting because of new programs.
 - The cost impacts of the current delivery system.
 - Minimum operating volumes to maintain financial viability.

In conclusion, the HMA report mixes data and opinion, places stronger emphasis on Level C data than Level B, and picks and chooses recommendations/findings from referenced data to support its conclusions. While we have chosen in this letter not to analyze each specific statement and recommendation in detail, we are in the process of finalizing such a document and are willing/prepared to share it with the Department if it would find it useful in moving forward with rulemaking.

Each of the hospitals listed below, as well as numerous others that have contacted us over the past three weeks want to reiterate for the record their full and committed intent to participate in good faith in the rule-making process to implement SHB 2304 by July 1, 2008. While the consensus is that the process would be streamlined if the HMA report were revised, we are prepared to work closely with the Department and other interested parties to develop rules utilizing recommendations that can be tied directly to relevant data and do this in partnership with experts in interventional cardiology and those who have in-depth knowledge of the current system in Washington. Again, the principles of evidence-based medicine require the integration of *"individual clinical expertise with the*

In closing, we want to thank the Department again for its efforts in this process and look forward to working with you through this rule development process.

Thank you again for the opportunity to comment.

On behalf of:

Auburn Regional Medical Center

Capital Medical Center

Franciscan Health System (St. Joseph Medical Center, St. Clare Hospital, St. Francis Hospital)

Good Samaritan Healthcare

Highline Medical Center

Kennewick Public Hospital District, Kennewick General Hospital

King County Public Hospital District #1, Valley Medical Center

King County Public Hospital District #2, Evergreen Healthcare

Legacy Salmon Creek Hospital

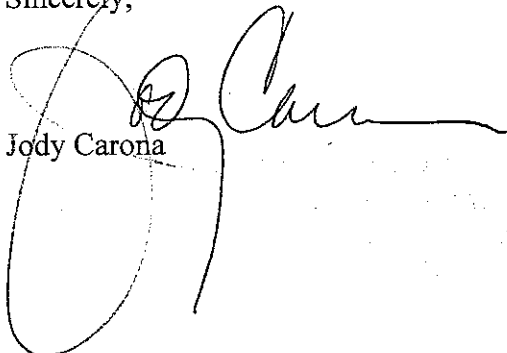
Skagit County Public Hospital District #1, Skagit Valley Hospital

Snohomish County Public Hospital District #2, Stevens Healthcare

Yakima Valley Memorial Hospital

As well as numerous other hospitals and health care entities supportive of a truly evidence-based process being used to inform this much needed rulemaking.

Sincerely,



Jody Carona